DEPARTMENT OF HEALTH AND HUMAN SERVICES

[redacted]

mail code HFI-35

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-30977
Telephone: (513) 679-2700
FAX: (513) 679-2761

May 7, 1999

WARNING LETTER
CIN-WL-99-161

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Cary J. Nolan, President
Picker International Inc.
595 Miner Road
Cleveland, OH 44143

Dear Mr. Nolan:

On January 20-29, 1999, the Food and Drug Administration (FDA) conducted an inspection of your firm which produces devices employing magnetic resonance, nuclear medicine and computed tomography technology. The articles are devices as defined by Section 201(h) of the Federal Food, Drug & Cosmetic Act (the Act).

The investigators found deviations from the Quality System Regulations (Q.S.R.) for medical devices as listed in Part 820 of Title 21, Code of Federal Regulations, (CFR). This causes your device equipment to be adulterated within the meaning of Section 501(h) of the Act in that the methods used in or the facilities or controls used for manufacturing, packing and storage are not in conformance with the Q.S.R.

The following deviations from the Device Quality System Regulations were documented:

1) Failure to maintain a design file necessary to demonstrate that the design was developed in accordance with the approved design plan as required by 21 CFR 820.30(j). For example, there is no documentation of any module testing of the gantry control module of the [redacted] Software. Procedure NENG 2304, 10/15/96, Software Design and Development Control System identifies module testing as a required task.

2) Failure to establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation as required by 21 CFR 820.30(b). For example:

   (a) Coding conventions, rules or procedures; e.g., addressing requirements for source code clarity, management of source complexity, and proper and safe use of the programming language; were not established for the implementation of the software component of the Axis/Irix Product, Project #NU1078, as indicated by procedure NENG 2304, 10/15/96, Software Design and Development Control System

(b) The Axis/Irix Alpha Test plan and procedures lacks documentation identifying how test cases are mapped to the corresponding element of the specification as required by procedure NENG 2304, 10/15/96, Software Design and Development Control System (8.2).

(c) The MR Work instruction Software Product Design Management, No. E084, lacks requirements for complete software specifications, unit testing, test case identification methodologies which assure testing rigor, and lacks test completion criteria such as test coverage or thoroughness requirements.

3. Failure to establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient, as required by21 CFR 820.30(c). For example:

(a) The MR division procedure, Design Program Management, No M2803 lacks a mechanism for addressing incomplete, ambiguous or conflicting design requirements.

(b) There is not an autonomous specification for the gantry control module of the [redacted] Software component for the Axis/Irix devices. Procedure NENG 2304, 10/15/96, Software Design and Development Control System requires a "Software Design Description" which documents software specification (5.2) in sufficient detail to permit coding and module testing (7.3.2).

(c) There is not an autonomous complete software specification for the [redacted]

(d) The Axis/Irix Product Specification – Base Development Project #NU1078, Product Specification (CP3) – Rev B; states in 17.1, "The [redacted] software specification is part of the rest of this specification and does not need to be delineated separately." However, the product specification lacks necessary detail to ensure correct software implementation the thorough software test coverage as illustrated by #2.2.2.1. OVERRIDE/RESET and a user discovered software problem where a cold restart was necessary in order to remove a patient from the device after a camera head hit the patient. This specification covers the functions of the Override/Reset button which failed to function as expected per this complaint, #IR056-99. This specification section contains the ambiguous word "all" which is not further specified elsewhere in this document or in another specification document, nor is there a cross reference to other relevant sections such as any defining the intended software functionality and performance in relation to activation of the contact sensors. There is no information which specifies sensor activation as an interrupt event.

4. Failure to establish and maintain procedures for verifying the device design as required by 21 CFR 820.30(f). For example:

(a) There is no documentation that all of the Axis/Irix [redacted] Communication Error Messages were exercised by testing.

(b) The only test completion criteria identified in the Axis/Irix Alpha Test Reports is the resolution of all major open problems. Criteria for testing rigor (e.g., identifying appropriate challenges) and/or thoroughness (e.g. structural and functional coverage criteria) are not documented.

(c) The test documentation lacks the necessary detail for objective review, and accurate repetition of tests. For example, "Cause collision throughout several whole body scans and confirm that the scans can be continued" does not identify the precise number of scans, number of collisions, or timing of the collisions. Test results are documented only as Pass or Fail and some comments.

(d) There is no test documentation, e.g., a test plan or actual test results, of the 8.4.15 (8.4E) version of the Odyssey software.

The inspection also disclosed that since January 1997 sixty-four mandatory and compulsory service letters were issued directing the field service organization to make repairs to distributed devices. Eight of these actions appear to be problems with the devices that if not corrected could trigger regulatory action. Information submitted to the CIN-DO Recall Coordinator for the eight actions were determined to be recalls. We believe these recalls which occurred after May 18, 1998 fit the criteria for reporting under Section 519(f) and should have been reported under such.

We acknowledge receipt of the March 3, 1999 letter from Robert L. Turocy, Regulatory and Compliance Manager, which responds to the FDA-483, Inspectional Observations, issued at the close of the FDA QSR Inspection of January 1999. While addressed to a limited degree, our concerns expressed about design control need to be further clarified. We note the corrections that you have made in the nuclear medicine division. We believe your response should be updated to show whether or not corrections were made by April 30, 1999. These promised corrections included: software product specifications and test plans for the software version 8.4; Quality Standard Procedures generated on how software is written and how software modules are defined and controlled (include complexity control, usage guidelines and source code tools).

We also note the changes made in the magnetic resonance division. Please provide a copy of the revised procedure M1022.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this into account when considering the award of contracts. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office within fifteen days of receipt of this letter of the specific steps you will be taking to comply with our request.

Your response should be sent to Lawrence E. Boyd, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237.

Sincerely,

Henry L. Fielden
District Director
Cincinnati District

cc: Robert L. Turocy
Regulatory Affairs and Compliance Manager